Calendar No. 946

106TH CONGRESS
2D SESSION

S. 1495

[Report No. 106–496]

To establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new and revised toxicological tests that protect human and animal health and the environment while reducing, refining, or replacing animal tests and ensuring human safety and product effectiveness.

IN THE SENATE OF THE UNITED STATES

AUGUST 4, 1999

Mr. DEWINE (for himself, Mr. SMITH of New Hampshire, Mrs. MURRAY, Mr. SANTORUM, Mrs. BOXER, and Mr. ABRAHAM) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

OCTOBER 11 (legislative day, SEPTEMBER 22), 2000

Reported by Mr. JEFFORDS, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new and revised toxicological tests that protect human and animal health and the environment while reducing, refining, or replacing animal tests and ensuring human safety and product effectiveness.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''ICCVAM Authorization Act of 1999''.

SEC. 2. INTERAGENCY COORDINATING COMMITTEE ON THE VALIDATION OF ALTERNATIVE METHODS.

(a) IN GENERAL.—The Interagency Coordinating Committee on the Validation of Alternative Methods (referred to in this Act as ''ICCVAM'') shall be sustained as a permanent standing committee and continued to be administered by the National Institute of Environmental Health Sciences. The purposes of ICCVAM shall be to—

(1) increase the efficiency and effectiveness of Federal agency test method review;

(2) eliminate duplicative efforts and share experiences across Federal regulatory agencies;

(3) optimize utilization of scientific expertise outside the Federal Government;

(4) ensure that new test methods meet the needs of Federal agencies; and

(5) reduce, refine, and replace the use of animals in testing.

(b) COMPOSITION.—ICCVAM shall be comprised of a representative from each of the following agencies and organizations:

(1) Agency for Toxic Substances and Disease Registry.

(2) Consumer Product Safety Commission.

(3) Department of Agriculture.

(4) Department of Defense.

(5) Department of Energy.

(6) Department of the Interior.

(7) Department of Transportation.

(8) Environmental Protection Agency.

(9) Food and Drug Administration.

(10) National Institute for Occupational Safety and Health.

(11) National Institutes of Health.

(12) National Cancer Institute.

(13) National Institute of Environmental Health Sciences.

(14) National Library of Medicine.

(15) Occupational Safety and Health Administration.

(16) Any other agency that develops, employs, or regulates the use of animals in toxicity testing.

(c) SCIENTIFIC ADVISORY COMMITTEE.—

(1) ESTABLISHMENT.—In addition, the National Institute of Environmental Health Sciences shall establish a Scientific Advisory Committee to assist ICCVAM and the National Institute of Environmental Health Sciences. The Committee shall be composed of at least one knowledgeable representative having a history of expertise, development, or evaluation in alternatives to animal toxicological tests, from each of the following interests:

(A) The personal care, pharmaceutical, industrial chemicals, agriculture, and any other regulated industry.

(B) A national animal protection organization established under section 501(c)(3) of the Internal Revenue Code of 1986.

(2) MEMBERSHIP.— The National Institute of Environmental Health Sciences shall also invite to be members of the Scientific Advisory Committee representatives from other stakeholder organizations such as:

(A) An academic institution.

(B) A State government agency.

(C) An international regulatory body.

(D) A corporation developing or marketing alternative test methodologies including contract laboratories.

(d) DUTIES.—ICCVAM shall carry out the following duties consistent with the protection of public health and the environment and for the purpose of reducing, refining, and replacing the use of animals in acute and chronic toxicological tests:

(1) Review and evaluate existing and new alternative methods, including batteries of tests and test screens, which may be acceptable for specific regulatory uses, including the coordination of technical reviews of proposed new or revised test methods of interagency interest.

(2) Facilitate interagency and international harmonization of acute chronic toxicological test protocols that encourage the reduction, refinement, or replacement of animal tests.

(3) Facilitate, promote, and provide guidance on development of validation criteria and processes for new methods and help promote the acceptance of such methods and awareness of accepted methods by Federal agencies and other stakeholders.

(4) File formal recommendations with each appropriate Federal agency identifying specific agency

guidelines, recommendations, or regulations for each new test, battery of tests, test screen, or end point reviewed by ICCVAM that may be appropriate for the reduction, refinement, or replacement of an animal test required or recommended by that Federal agency for compliance with that agency's specific statutes, regulations, or guidelines. Tests may be recommended for a certain class of chemicals within that regulatory framework.

(5) Consider for review and evaluation, petitions received from the public which identify a specific regulation, recommendation, or guideline, and which recommend alternatives and provide scientific evidence of the acceptability of the alternatives for the purpose of carrying out the regulatory mandate in question.

(6) Make final recommendations to agencies and responses from agencies available to the public.

(7) Make an annual report to be made available to the public on its progress to promote the regulatory acceptance of new and revised toxicological tests.

SEC. 3. APPLICATION.

This Act shall not apply to regulations, guidelines, or recommendations related to medical research. The term

''medical research'' means research, including research performed using biotechnology, related to the causes, diagnosis, treatment, or control of physical or mental impairments of humans or animals. The term does not include the testing of a product to determine its toxicity for the purpose of complying with protocols, recommendations, or guidelines for testing required, recommended, or accepted by a Federal regulatory agency for a product introduced in commerce.

SEC. 4. FEDERAL AGENCY ACTION.

(a) IDENTIFICATION OF TESTS.—Within 180 days after the date of enactment of this Act, each Federal agency authorized to carry out a regulatory program which requires or recommends acute or chronic toxicological testing shall identify any regulation or industry-wide guideline which specifically, or in practice requires, recommends, or encourages the use of an animal acute or chronic toxicological test and shall forward to ICCVAM a list of these regulations, guidelines, and recommendations along with the test or tests recommended or required.

(b) ALTERNATIVES.—Each Federal agency shall promote and encourage the development and use of alternatives to animal tests, including batteries of tests and test screens, where appropriate, for the purpose of complying with Federal regulations, guidelines, or rec-

ommendations, in each instance, and for each chemical class, for which such tests are found to be effective for generating data at least equivalent for hazard identification or dose-response assessment purposes to the method established under the current regulatory scheme.

(c) TEST VALIDATION.—Each Federal agency shall ensure that any new acute or chronic toxicity test, including animal tests and alternatives, is determined to be valid for its proposed use prior to requiring, recommending, or encouraging its application.

(d) REVIEWS.—Each Federal agency shall review any formal recommendations from ICCVAM to promulgate new regulations or draft new guidelines or recommendations to promote the ICCVAM recommendations and notify ICCVAM in writing of its findings within 180 days of receipt of the recommendations.

(e) RECOMMENDATION ADOPTION.—Each Federal agency shall adopt the ICCVAM recommendations unless each individual Federal agency determines that—

(1) the alternative is not adequate in terms of biological relevance for the regulatory goal authorized by that agency;

(2) the alternative does not generate data at least equivalent for the appropriate hazard identi-

~~fication or dose-response assessment purpose as the method recommended by that agency;~~

~~(3) that agency does not employ, recommend, or require testing for that class of chemical or for the recommended end point; or~~

~~(4) the new test method is unacceptable for satisfactorily fulfilling the test needs for that particular agency and its respective congressional mandate.~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "ICCVAM Authorization Act of 2000".

SEC. 2. DEFINITION.

In this Act the term "alternative test method" means a test method that—

(1)(A) reduces the number of animals required;

(B) refines procedures to lessen or eliminate pain or distress to animals, or enhances animal well-being; or

(C) replaces animals with non-animal systems or 1 animal species with a phylogenetically lower animal species, such as replacing a mammal with an invertebrate; and

(2) includes any new or revised test method that is developed for use after the date of enactment of this

Act and proposed as an alternative to a traditional method.

SEC. 3. INTERAGENCY COORDINATING COMMITTEE ON THE VALIDATION OF ALTERNATIVE METHODS.

(a) IN GENERAL.—The Interagency Coordinating Committee on the Validation of Alternative Methods (referred to in this Act as "ICCVAM") shall be a permanent standing committee administered by the National Institute of Environmental Health Sciences of the National Institutes of Health under the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods.

(b) PURPOSES.—With respect to the use of animals in toxicological tests, the purposes of ICCVAM described in subsection (a) shall be to—

(1) increase the efficiency and effectiveness of Federal agency test method review;

(2) eliminate duplicative efforts and share experiences between Federal regulatory agencies;

(3) optimize utilization of scientific expertise outside the Federal Government;

(4) ensure that new and revised test methods are validated to meet the needs of Federal agencies; and

(5) reduce, refine, and replace the use of animals in testing.

(c) COMPOSITION.—The ICCVAM described in subsection (a) shall be comprised of representatives from each of the following:

(1) Agency for Toxic Substances and Disease Registry.

(2) Consumer Product Safety Commission.

(3) Department of Agriculture.

(4) Department of Defense.

(5) Department of Energy.

(6) Department of the Interior.

(7) Department of Transportation.

(8) Environmental Protection Agency.

(9) Food and Drug Administration.

(10) National Institute for Occupational Safety and Health.

(11) National Institutes of Health.

(12) National Cancer Institute.

(13) National Institute of Environmental Health Sciences.

(14) National Library of Medicine.

(15) Occupational Safety and Health Administration.

(16) Any other agency that develops, or employs tests or test data using animals, or regulates on the basis of the use of animals in toxicity testing.

(d) SCIENTIFIC ADVISORY COMMITTEE.—

(1) ESTABLISHMENT.—The National Institute of Environmental Health Sciences shall establish a Scientific Advisory Committee (referred to in this Act as the "SAC") to advise the ICCVAM described in subsection (a). The activities of the SAC shall be subject to provisions of the Federal Advisory Committee Act.

(2) MEMBERSHIP.—The SAC described in paragraph (1) shall be composed of—

(A) at least 1 knowledgeable representative having a history of expertise, development, or evaluation of new or alternative test methods from each of—

(i) the personal care, pharmaceutical, industrial chemicals, or agriculture industry, and any other industry that is regulated by the Federal agencies described in subsection (c); and

(ii) a national animal protection organization established under section 501(c)(3) of the Internal Revenue Code of 1986; and

(B) representatives (selected by the National Institute of Environmental Health Sciences) from an academic institution, a State government agency, an international regulatory body,

or any corporation developing or marketing new or alternative test methodologies, including contract laboratories.

(e) DUTIES.—The ICCVAM described in subsection (a) shall, consistent with the purposes described in subsection (b)—

(1) review and evaluate existing and new alternative test methods, including batteries of tests and test screens, that may be acceptable for specific regulatory uses, including the coordination of technical reviews of proposed new or revised test methods of interagency interest;

(2) facilitate appropriate interagency and international harmonization of acute and chronic toxicological test protocols that encourage the reduction, refinement, or replacement of animal tests;

(3) facilitate, promote, and provide guidance on the development of validation criteria, validation studies and processes for new and revised methods and help promote the acceptance of such methods and awareness of accepted methods by Federal agencies and other stakeholders;

(4) file formal recommendations with each appropriate Federal agency identifying specific agency guidelines, recommendations, or regulations for each

new test, battery of tests, test screen, or endpoint reviewed by the ICCVAM that may be appropriate for the reduction, refinement, or replacement of an animal test required or recommended by that Federal agency for compliance with that agency's specific statutes, regulations, or guidelines, including filing recommendations for tests for a certain class of chemicals within a regulatory framework;

(5) consider for review and evaluation, petitions received from the public that identify a specific regulation, recommendation, or guideline, and that recommend alternatives and provide scientific evidence of the potential of the alternatives for the purpose of carrying out the regulatory mandate in question;

(6) make final recommendations to agencies and make the responses from agencies regarding the final recommendations available to the public; and

(7) prepare an annual report to be made available to the public on its progress to promote and assess validation of new and revised toxicological tests.

SEC. 4. FEDERAL AGENCY ACTION.

(a) IDENTIFICATION OF TESTS.—Not later than 180 days after receipt of an ICCVAM test recommendation, each Federal agency carrying out a program that requires or recommends acute or chronic toxicological testing shall—

(1) identify any relevant test requirement specified in a regulation or industry-wide guideline which specifically, or in practice requires, recommends, or encourages the use of an animal acute or chronic toxicological test for which the ICCVAM test recommendation may be added or substituted; and

(2) forward the identification of such test to the ICCVAM.

(b) ALTERNATIVES.—Each Federal agency shall promote and encourage the development and use of alternatives to animal tests (including batteries of tests and test screens, where appropriate) for the purpose of complying with Federal statutes, regulations, guidelines, or recommendations (in each instance, and for each chemical class) if such tests are found to be effective for generating data, in an amount and of a scientific value that is at least equivalent to the data generated from existing tests, for hazard identification, dose-response assessment, or risk assessment purposes.

(c) TEST VALIDATION.—Each Federal agency shall ensure that any new or revised acute or chronic toxicity test, including animal tests and alternatives, is determined to be valid for its proposed use prior to requiring, recommending, or encouraging the application of such test.

(d) REVIEW.—Not later than 180 days after receipt of a formal recommendation from the ICCVAM, each Fed-

eral agency shall review such recommendation and notify the ICCVAM in writing of its findings.

(e) RECOMMENDATION ADOPTION.—Each Federal agency, or its specific regulatory unit or units, shall adopt the ICCVAM recommendation unless such Federal agency determines that—

(1) the ICCVAM recommendation is not adequate in terms of biological relevance for the regulatory goal authorized by that agency, or mandated by Congress;

(2) the ICCVAM recommendation does not generate data, in an amount that is at least equivalent to the data generated prior to such recommendation, for the appropriate hazard identification, dose-response assessment, or risk assessment purposes as the method recommended or required by that agency;

(3) the agency does not employ, recommend, or require testing for that class of chemical or for the recommended endpoint; or

(4) the new or revised test method is unacceptable for satisfactorily fulfilling the test needs for that particular agency and its respective congressional mandate.

SEC. 5. APPLICATION.

(a) APPLICATION.—This Act shall not apply to research, including research performed using biotechnology techniques, or research related to the causes, diagnosis, treatment, control, or prevention of physical or mental diseases or impairments of humans and animals using medically accepted methodologies.

(b) USE OF TEST METHODS.—Nothing in this Act shall prevent a Federal agency from retaining final authority for incorporating the test methods recommended by the ICCVAM in the manner determined to be appropriate by such Federal agency or regulatory body.

(c) LIMITATION.—Nothing in this Act shall be construed to require a manufacturer that is currently not required to perform animal testing to perform such tests. Nothing in this Act shall be construed to require a manufacturer to perform redundant, endpoint, specific testing.

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